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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,358	11/26/2001	Jules Zecchino	2870/566	2755

7590

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KAREN A. LOWNEY, ESQ.
ESTEE LAUDER COMPANIES
125 PINELAWN ROAD
MELVILLE, NY 11747

EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 10/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant N .

09/995,358

Applicant(s)

JULES ZECCHINO ET AL

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 July 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- ☐ Interview Summary (PTO-413) Paper No(s). _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other:

DETAILED ACTION

Examiner acknowledges receipt of request for extension of time and response filed 07/22/02.

Claim Rejections - 35 USC § 102

1. The rejection of claims 1, 3, 5 and 8 under 35 U.S.C. 102(b) as being anticipated by Wheeler (WO 97/32559) is withdrawn in light of the arguments presented in the response.

Claim Rejections - 35 USC § 103

2. Claims 1, 3-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wheeler (WO 97/32559) and Collin et al. (US 5,667,789).

Applicants agree that the composition is a bi-liquid foam dispersed in an aqueous gel.

Applicants say that they unexpectedly found that one particular gelling agent, namely, a polymeric sulfonic acid was capable of maintaining stable dispersion of bi-liquid foam at low pH's. Furthermore, applicants agree that while Wheeler teaches dispersion of bi-liquid foam in an aqueous gel, the reference does not address the issue of incorporating acidic components into the formulation. Wheeler according to the applicants discloses standard gelling agents and not polymeric sulfonic acid. Finally, applicants state that Collin does not teach a bi-liquid foam and that Collin does not fill the missing pieces from the Wheeler reference because the authors of the Collin reference only claimed to have prepared stable salicylic acid.

3. Applicant's arguments filed 07/22/02 have been fully considered but they are not persuasive.

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Regarding the unexpected result, applicants failed to provide the unexpected result they claim to have. Applicants provided no data comparing bi-liquid foam dispersed in an aqueous gel stabilized with the standard gelling agent and one stabilized with the polymeric sulfonic acid. There is no comparison between the composition of the prior art and the instant composition.

Regarding the Collin reference, the Collin reference is relied upon for a teaching of a salicylic acid or salicylic acid derivatives in a cosmetic composition. Regarding Wheeler's failure to include acidic components in the formulation, the Collin reference is relied upon for a teaching of salicylic acid which is one of the acids recited in claim 5.

Wheeler teaches cosmetic or pharmaceutical composition comprising a stable dispersion that comprises oil-based bi-liquid foam and an aqueous gel. The oil-based bi-liquid foam of Wheeler comprises from 1% to 80% by weight of the total formulation. The composition of Wheeler also comprises silicone oils wherein the oils can be cyclomethicone, dimethicone, dimethicone copolyol, lanolin and dimethiconol. Wheeler teaches a formulation further comprising from 0.05% to 0.5% of surfactant and active ingredient in the aqueous or oily phase. Wheeler teaches that the low level of surfactant incorporated into the formulation comprises quaternary ammonium sulfonium salts, amphoteric surfactant, anionic surfactant, alpha-olefin sulfonate, and ester-linked sulfonate. Salts of cross-linked polymers of acrylic acid (carbomers), glyceryl polymethacrylates, or copolymers of polyoxyethylene/polyoxypropylene in mixtures with the previously listed surfactants may serve as gelling agents. Wheeler's composition (example 3) comprises citric acid and the composition is adjusted to pH 6.5 (less than pH 7). See page 3, paragraph 2 to page 5 paragraph 2.

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However, Wheeler failed to teach alpha-hydroxy acids or beta-hydroxy acids as active agents. But Collin teaches oil-in-water cosmetic composition comprising salicylic acid, salicylic acid derivatives, silicone containing oil (cyclomethicone), octyl palmitate and the oils comprising 10% to 70% by weight of the total emulsion. Collin et al. further teaches the composition to comprise carboxyvinyl polymers and carbomers gelling agents in amounts of 0.1% to 10%.

Wheeler teaches pharmaceutical and cosmetic composition comprising bi-liquid foam that further comprises active ingredients, silicone oil, sulfonate salts, surfactants and gelling agents. Collin teaches cosmetic composition comprising salicylic acid active ingredient, silicone oil and gelling agents in an oil-in-water emulsion. Collin also teaches that the salicylic acid stabilizes oil-in-water emulsions. See column 1, line 7 to column 5, and line 2.

In the case where the compositions of prior art are used for the same purpose, in this instance, cosmetic, "it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Wheeler in the manner disclosed by Collin. One having ordinary skill in the art would have been motivated to prepare the composition of Wheeler et al. and incorporate the salicylic acid of Collin et al. wherein the salicylic acid is the active ingredient and further stabilizes the bi-liquid foam. The amount of the bi-liquid foam of the instant invention overlaps with amount of the bi-liquid form disclosed

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by Wheeler et al. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). It is not critical how a composition is made. The invention is obvious over the prior art in the absence of a showing of unexpected result over the prior art.

4. Claims 1, 2 and 12-21 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wheeler (WO 97/32559) and Collin et al. (US 5,667,789) in view of Clariant product brochure.

5. Applicants agree that the Clariant reference does not address the issue of low pH and that there is no expectation of success in formulating the combined composition of Wheeler and Collin with the gellant in the Clariant product brochure.

Applicant's arguments filed 07/22/02 have been fully considered but they are not persuasive.

The Clariant brochure does teach that the polymeric sulfonic acid provides thickening even at low pH's and Wheeler teaches low pH. The brochure describes a product that is a good gelling agent or thickening agent. One of skill or ordinary skill in the art would be motivated to try out the gelling agent in the brochure that is described as a good gelling agent or thickening agent and one that can thicken even at low pH's in emulsions. Emulsions are specifically mentioned in the brochure. The expectation of success is high since the specific agent thickens emulsions. Applicants provided no data that shows that the gelling or thickening agent disclosed in the brochure would not work in Wheeler or Collin or the combined formulation of Wheeler and Collin or comparative data between the prior art composition and the instant composition.

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Wheeler and Collin are discussed in the preceding rejection. Although, Wheeler suggests ammonium sulfonate salt gelling agent, and Wheeler and Collin both teach the incorporation of gelling agent into the formulation, they failed to teach the specific gelling agent Aristoflex AVC or copolymer of polyacryldimethyltauramide and vinylformamide. But the Clariant product brochure teaches Aristoflex AVC or copolymer of polyacryldimethyltauramide and vinylformamide gelling agent for aqueous systems and thickening agent for oil-in-water emulsions. It would have been obvious to one having ordinary skill in the art at the time the invention was made and one motivated to prepare the composition of Wheeler and Collin to use the commercial gelling agent disclosed in the Clariant product brochure in the composition of the prior art.

Wheeler's composition is adjusted to pH 6.5, which is less than pH 7. In the absence of a showing of unexpected result over the prior art, the invention is not critical over the prior art.

No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Observation: Applicants have provided no information disclosure statement and PTO 1449.

7. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification and in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
October 10, 2002


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600